

CA 1:1 EVO.15 1:1
CA 1:5 EVO.15 1:5
CA 10:1

ENG Instructions for use

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www.bienair.com/ifu



CE
0120

REF 2100294-0000/2015.02

Set supplied (REF) CA 1:5



1600386-001



1600325-001



1600690-001



1600941-001



1600940-001

Set supplied (REF) CA 1:1



1600384-001



1600424-001



1600691-001



1600939-001



1600938-001

Set supplied (REF) CA 10:1



1600385-001



1600425-001

Optional accessories (REF)



1600036-006



1600064-006



1000001-010

















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ENG Instructions for use

1 Symbols

1.1 Description of symbols used

Symb	Description	Symb	Description
	Manufacturer.		Reference number.
	CE Marking with number of the notified body.		Serial number.
	CAUTION!		Electrical or electronic materials to be recycled.
	Refer to the accompanying documents.		Recyclable materials.
	Light.		Use rubber gloves.
	Sterilisable in an autoclave up to the specified temperature.		Cleaning in machine authorised.
	Movement in the direction indicated.		After initial mechanical resistance, fully tighten in the direction indicated.
	Movement to the stop in the direction indicated.		Back and forth movement.

2 Identification & Intended Use

2.1 Identification

Medical devices made entirely in Switzerland by Bien-Air Dental SA.

Type

Dental contra-angles (CA), push-button bur locking, 3 sprays (4 mixed sprays on the EVO.15 range) with or without light.

Classification

Class IIa according to European Directive 93/42/EEC relating to medical devices. This medical device complies with the legislation in force.

2.2 Intended use

This product is intended solely for professional use.

For use in dentistry:

- CA 1:1, CA 10:1 and EVO.15 1:1: for prophylaxis, restoration and endodontic procedures.
- CA 1:5 and EVO.15 1:5: for general dentistry and restoration procedures.

CAUTION

Any use other than that for which this device is intended is prohibited and may prove dangerous.

CAUTION

The device must not be used if any open lesions or damaged soft tissue are present or if a recent extraction has taken place. The air current could propel infected material into the wounds, causing infection and a risk of embolism.

3 Precautions for use

This medical device accessory must be used by a competent person, in particular in compliance with the legal provisions in force regarding occupational safety, health and accident prevention measures, and these instructions for use.

In accordance with these provisions, the user is responsible for ensuring he or she only uses devices which are in perfect working order.

In the event of irregular operation, excessive vibrations, abnormal heating or other signs suggesting that the device is malfunctioning, work must be suspended immediately.

In this case, contact a repair centre approved by Bien-Air Dental SA.

CAUTION

Install the device on an appropriate outlet to protect against the risk of injury or infection.

CAUTION

The universal precautions, in particular wearing of personal protective equipment (gloves, goggles, etc.), should be complied with by medical personnel using or performing maintenance on medical devices that are contaminated or potentially contaminated. Pointed and sharp instruments should be handled with great care.

CAUTION

Any excess maintenance product (lubricant, cleaning and disinfection products) present on the contra-angle could find its way into the electric brush motor and adversely affect its operation.

Always observe the maintenance instructions provided with each product. Never lubricate the electric brush motor.

CAUTION

To avoid adversely affecting the device's service life, ensure purified, dry compressed air is used.

Ensure the quality of the air and water being supplied through regular maintenance of the compressor and the filtration systems.

Note: *Using unfiltered hard water will speed up blockage of the hoses, couplings and spray diffusers.*

Note: *The technical specifications, illustrations and dimensions contained in these instructions are given merely as an indication. They may not give rise to any claim. For any further information, please contact Bien-Air Dental SA at the address given on the back cover.*



FIG. 1 (EVO.15 1:1 L)

4 Description

4.1 Overview

FIG. 1

- (1) Centring for the micromotor
- (2) Light outputs
- (3) Bur (not supplied)
- (4) Transmission ratio marking strip
- (5) Push-button

4.2 Technical data

Transmission ratio	1:1	1:5	10:1
Standard coupling	As per ISO standard 3964 and Micro-Series version.		
Transmission ratio	Direct ratio, blue strip	Speed increasing ratio of 5, red strip	Speed decreasing ratio of 10, green strip
Drive speed	40,000 rpm max.	40,000 rpm max.	40,000 rpm max.
Speed of rotation.	40,000 rpm max.	200,000 rpm max.	4000 rpm max.
Weight	87g (1:1 L) 86g (1:1) 79g (1:1 L Micro-Series) 84g (EVO.15 1:1L) 76g (EVO.15 1:1L Micro-Series)	90g (1:5 L) 89g (1:5) 82g (1:5 L Micro-Series) 88g (EVO.15 1:5L) 80g (EVO.15 1:5 L Micro-Series)	86g (10:1 L) 85g (10:1)
Length	97 mm (88 mm for Micro-Series versions)		
Air consumption	8 - 10 NL/min	8 - 10 NL/min	8 - 10 NL/min

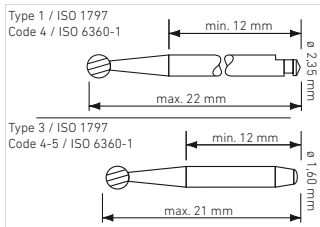


FIG. 2

Bur

FIG. 2

- Tip diameter 2.35 mm, type 1 as per ISO 1797-1, max length 21 mm code 4 as per ISO 6360-1 for the 1:1 and 10:1 range.
- Tip diameter 1.60 mm, type 3 as per ISO 1797-1, max length 22 mm code 4/5 as per ISO 6360-1 for the 1:5 range.

⚠ CAUTION

Follow the guidelines for use, according to the tool manufacturer's instructions. Never use a bur if the tip is not compliant, as there is a risk it can become detached during the procedure and injure the practitioner, the patient or third parties.

5 Assembly and operation

5.1 Changing the bur

FIG. 3

Push-button bur locking.

1. Press the push-button and simultaneously pull the bur.
2. Press the push-button, insert the new bur until locked in place and release the push-button.

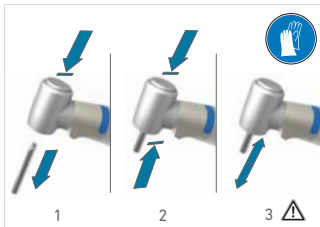


FIG. 3

3. Check it is correctly locked by gently pushing and pulling the bur.

⚠ CAUTION

Always check that the bur is in place and rotates freely. If it does not, contact your usual supplier or Bien-Air Dental SA for repair.

5.2 Operation

⚠ CAUTION

Do not operate the device until a bur has been inserted.

To prevent the push-button from overheating, which could lead to burns, it must not be pressed accidentally when the device is rotating. Soft tissue (tongue, cheek, lips, etc.) must be protected by moving it away using a retractor or dental mirror.

⚠ CAUTION

Never insert a device on a rotating micromotor.

⚠ CAUTION

Always ensure that the spray outlets are not obstructed.

6 Cleaning and servicing


6.1 Maintenance

Clean, lubricate and sterilise the device separately between patients.

CAUTION

The instrument is supplied "non sterile".

6.1.1 Precautions for maintenance

- Before first use and IMMEDIATELY after each procedure, clean, disinfect and lubricate the device, then sterilise it. Observing this procedure eliminates any blood, saliva or saline solution residues and prevents the transmission system from being blocked.
- Only instruments marked with the  logo can be cleaned in a washer-disinfector machine.
- Do not immerse in an ultrasonic cleaner.
- Only use original Bien-Air Dental maintenance products and parts or those recommended by Bien-Air Dental SA. Using other products or parts may cause faults during operation and/or void the warranty.

Bur chuck mechanism (cutting tool)

Carry out cleaning – disinfection – sterilisation without bur in the chuck mechanism.

6.1.2 Suitable maintenance products

Automatic cleaning-disinfection:

- Low alkaline or enzymatic detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 6 - 9.5).

Manual cleaning/disinfection

- Spraynet.
- Detergent or detergent-disinfectant (pH 6- 9.5) recommended for cleaning-disinfection of dental or surgical instruments. Surface-active quaternary enzymatic/ammonium detergent.

CAUTION

- Do not use detergents that are corrosive or contain chlorine, acetone, aldehydes or bleach.
- Do not submerge in physiological liquid (NaCl).
- Check that both the steriliser and water used are clean. After each sterilisation cycle, remove the device from the sterilisation unit immediately to reduce the risk of corrosion.



FIG. 4

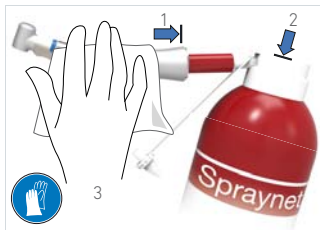


FIG. 5

6.2 Preliminary cleaning

Preparation

FIG. 4

1. Disconnect the coupling device, remove the bur (FIG. 3, step 1.).

⚠ CAUTION

If there is a large amount of debris, clean the exterior of the device with disinfectant wipes.

2. Unblock the spray tubes using the Bien-Air Dental SA cleaning wire.

3. Carry out manual preliminary cleaning (see 6.2.1, on page 8) or preliminary cleaning in a bath (see 6.2.2, on page 8).

6.2.1 Manual preliminary cleaning

FIG. 5

1. Disconnect the device from its coupling and remove the bur.

2. Spray the exterior and interior of the device for 1 second with Spraynet. Carefully clean the surfaces using a soft cloth. Disinfectant wipes may also be used.

3. Leave any liquid residue to drip-dry, then wipe the exterior with a paper towel or move onto the cleaning-disinfection step immediately (see 6.3, on page 9).

6.2.2 Preliminary bath cleaning

⚠ CAUTION

The preliminary bath cleaning should be followed by automatic cleaning-disinfection.

1. Totally submerge the device in a cleaning bath containing a suitable detergent as per the manufacturer's instructions (duration, concentration, temperature, renewal, etc.).

2. Rinse the interior and exterior of the device with demineralised water (< 38°C) for 30 seconds.

3. Leave to drip-dry and wipe the exterior surfaces with a paper towel or immediately proceed with automatic cleaning-disinfection (see 6.3.2, on page 9).



FIG. 6

6.3 Cleaning-disinfection

6.3.1 Manual cleaning/disinfection

1. Dip the device in a tank containing appropriate detergent and, using a soft brush, clean and disinfect the device, clean the exterior of the device in accordance with the instructions of the detergent manufacturer (time, concentration, temperature, renewal, etc.)


2. Rinse the interior and exterior of the device with demineralised water (< 38°C) for 30 seconds.

FIG. 6

3. Spray the interior of the device with Spraynet to remove the rinsing water immediately, which will prevent damage to or blockage of the internal components, then dry the exterior surfaces with paper towels.

6.3.2 Automatic cleaning-disinfection

⚠ CAUTION

Only for devices engraved with .

Washer-disinfector

Carry out automatic cleaning-disinfection using an approved washer-disinfector which complies with ISO standard 15883-1 (e.g. Miele G 7781/G 7881 or Steris Hamo LM-25).

Detergent and washing cycle

Use a low alkaline or enzymatic detergent recommended for cleaning in a washer-disinfector for dental or surgical instruments (pH 6 - 9.5) (e.g.: neodisher® mediclean).

Select the washing cycle recommended for the device and compatible with the detergent manufacturer's indications (e.g.: VARIO-TD)

⚠ CAUTION

Never cool devices by rinsing them.

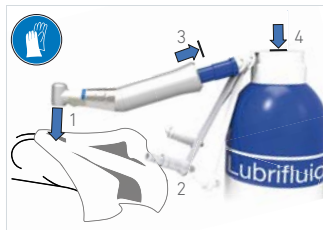


FIG. 7

6.4 Lubrication

6.4.1 Verifying cleanliness

Visually inspect the device to ensure it is clean. If necessary, clean again using a soft brush.

6.4.2 Lubrication

Lubricate before each sterilisation or at least twice a day. Only the Lubrifiuid spray must be used.

FIG. 7

1. Remove the bur from the device and place the device in a cloth to remove surplus lubricant.
2. Select the correct end-piece and remove the protective cap.
3. Insert the end-piece of the can Lubrifiuid in the rear of the device's handle.
4. Actuate the spray for 1 second, and clean the excess oil on the exterior.

6.5 Sterilisation

⚠ CAUTION

The quality of the sterilisation is highly dependent on how clean the device is. Only perfectly clean instruments may be sterilised.



FIG. 8

⚠ CAUTION

Do not use a sterilisation procedure other than the one described below.

Procedure

Enclose the device and its accessories in sterilisation bags which are large enough to ensure the items can move around, and which comply with the standards in force (e.g.: EN 868-5). Sterilise using steam on a class B cycle as per EN 13060 / ISO 17665-1.

Note : All Bien-Air Dental SA contra-angles are sterilisable in an autoclave up to 135°C. Duration: 3 or 18 minutes, depending on the national requirements in force.

FIG. 8

After cleaning, disinfecting and sterilising the device, and before using it, start it up at moderate speed with a bur in the locking mechanism (FIG. 3, step 2.) for 10 to 15 seconds to distribute and remove the excess lubricant.

6.6 Servicing

Never dismantle the device. For all servicing or repair operations, you are advised to contact your usual supplier or Bien-Air Dental SA directly.

Note : Bien-Air Dental SA recommends that the user has his or her dynamic devices checked or serviced regularly.

7 Packing and disposal

7.1 Transport and storage conditions

Temperature between -40°C and 70°C inclusive, relative humidity between 10% and 100%, atmospheric pressure between 50 kPa and 106 kPa.

7.1.1 Packing

Pack the instrument in packaging approved for steam sterilisation.

CAUTION

If not to be used for a prolonged period, the device must be stored in a dry environment. Clean, lubricate and sterilise the instrument before reuse.

7.2 Disposal



The disposal and/or recycling of materials must be performed in accordance with the legislation in force.



The CA and its accessories must be recycled. Electrical and electronic equipment may contain dangerous substances which constitute health and environmental hazards.

Users should return devices to their distributors or directly contact an approved body responsible for processing and recovering this type of equipment (European directive 2002/96/EC).

8 General information

8.1 Terms of guarantee

Bien-Air Dental SA grants the user a warranty covering any operating fault, or material or manufacturing defect.

The warranty period is:

- 12 months for the CA 10:1 range
- 24 months for the CA 1:1, CA 1:5 and EVO.15 ranges

from the date of invoicing.

In the event of a justified claim, Bien-Air Dental SA or its authorised representative will repair or replace the product free of charge.

All other claims of any kind whatsoever, particularly claims for damages or interest, are excluded.

Bien-Air Dental SA cannot be held liable for damage or injury and the consequences thereof, resulting from:

- Excessive wear
- Infrequent use
- Failure to observe the servicing, assembly or maintenance instructions
- Damage caused by unusual chemical, electrical or electrolytic influences
- Faulty air, water or electrical connections.

CAUTION

The warranty becomes null and void if damage and its consequences result from incorrect servicing or modification by third parties not authorised by Bien-Air Dental SA.

Claims under the terms of the warranty will be considered only on presentation, together with the product, of the invoice or the consignment note. The following information must be clearly indicated: The date of purchase, the product reference and the serial number.

8.2.2 Optional accessories (see cover)

REF	Legend
1600036-006	Spraynet, 500 ml cleaning spray, box of 6
1600064-006	Lubrifiant, 500 ml spray lubricant oil, box of 6
1000001-010	Cleaning wire, box of 10

8.2 References

Translated from original French Instructions for use.

8.2.1 Set supplied (see cover)

REF	Legend
1600939-001	EVO.15 1:1 L (light)
1600938-001	EVO.15 1:1 L Micro-Series (light)
1600941-001	EVO.15 1:5 L (light)
1600940-001	EVO.15 1:5 L Micro-Series (light)
1600384-001	CA 1:1 L (light)
1600424-001	CA 1:1 (without light)
1600385-001	CA 10:1 L (light)
1600425-001	CA 10:1 (without light)
1600691-001	CA 1:1 L Micro-Series (light)
1600386-001	CA 1:5 L (light)
1600325-001	CA 1:5 (without light)
1600690-001	CA 1:5 L Micro-Series (light)

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